IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* TO PRECLUDE THE TESTIMONY OF ALL DEFENDANTS' EXPERT WITNESSES OTHER THAN DR. GIBBONS CONCERNING THE FDA ALERT AND RELATED FDA SUBJECTS OR, IN THE ALTERNATIVE, TO PRECLUDE THE TESTIMONY OF DR. GIBBONS

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") respectfully submit this memorandum in opposition to Plaintiff's motion *in limine* to preclude "the testimony of all defendants' expert witnesses other than Dr. Gibbons concerning the FDA Alert and related FDA subjects or, in the alternative, to preclude the testimony of Dr. Gibbons." (Pl. Mem. [87] at 1.)

INTRODUCTION

In the case *Bulger v. Pfizer Inc.*, No. 1:04-10981-PBS, the MDL court previously addressed a substantially identical motion *in limine* filed by the plaintiff in that case, who was also represented by the same counsel. [MDL Docket Nos. 1887, 1888] The MDL court properly denied that motion on July 24, 2009, and this Court should likewise deny this substantially identical motion in this case for the same reasons. Here, as in *Bulger*, Plaintiff argues that because Pfizer represented that Dr. Gibbons, the only defense biostatistician who has rendered an opinion on the Alert and FDA's subsequent analysis, was "uniquely qualified" to opine about the Alert and the statistical analyses underpinning it, that was necessarily an admission that none of

Pfizer's other experts, including Drs. Arrowsmith, Ruggieri and Weiss Smith, are qualified to address the Alert in any respect whatsoever. But Plaintiff offers no evidence to support this argument. In fact, Plaintiff cites testimony from Pfizer's witnesses, suggesting that the witnesses are in fact qualified to comment generally on the FDA Alert.

Inexplicitly, Plaintiff also accuses Pfizer of making "misrepresentations" to the MDL court by arguing—contrary to her *Daubert* argument—that Drs. Arrowsmith, Ruggieri and Weiss Smith, were in fact capable of and qualified to address the Alert, obviating the need for a rebuttal witness. Thus, Plaintiff claims that Pfizer lied to the MDL court when it sought leave to name Dr. Gibbons as a rebuttal expert and that this Court should accordingly reconsider the MDL court's Order allowing Dr. Gibbons and strike him as an expert witness. Plaintiff's melodramatic allegations notwithstanding, this argument not only glosses over the disparate areas of expertise of Pfizer's witnesses, but also ignores the differences between the opinions of the experts, which Plaintiff, again lacking any evidence, refers to as "almost identical" and hence, "cumulative." Dr. Gibbons, for instance, is the only defense expert who performed biostatistical calculations analyzing the data underlying the Alert and meta-analysis—one of the express bases on which Pfizer sought leave to name him as a rebuttal expert. On the other hand, Drs. Arrowsmith, Ruggieri and Weiss Smith, none of whom are biostatisticians, offer no such statistical calculations, but instead comment on the FDA Alert and subsequent events as it relates to their opinions in the instant case.

Finally, Plaintiff claims that she was "surprised" when Drs. Arrowsmith, Ruggieri and Weiss Smith offered opinions about the FDA Alert in November 2008. But that these experts authored reports in November 2008 containing supplemental opinions is not surprising, nor did it violate the MDL court's scheduling orders as Plaintiff claims. The reports were timely served on November 10, 2008, in accordance with the MDL court's imposed deadline for service of expert reports in *Smith v. Pfizer* pursuant to a *joint* request for extension of deadlines.

ARGUMENT

I. The Fact That Dr. Gibbons Is Uniquely Qualified To Address The Statistical Underpinnings Of The FDA Alert Does Not Mean That Pfizer's Other Experts Are Unqualified To Opine Generally On The Alert

Plaintiff has offered no evidence whatsoever that Drs. Arrowsmith, Ruggieri and Weiss Smith are not qualified to opine on the FDA Alert. Instead, Plaintiff argues that because Pfizer previously stated that Dr. Gibbons was "uniquely qualified to opine on plaintiffs' experts' reliance on the Alert, as well as FDA's analysis and methodology and their scientific reliability" (Pl. Mem. at 2), none of Pfizer's other experts are qualified to opine about the FDA Alert in any capacity whatsoever. This argument strains logic.

Despite Plaintiff's suggestion, Pfizer has never even hinted that any of its experts are unqualified to generally address the Alert and how it may or may not impact their opinions in this case. Moreover, the fact that Dr. Gibbons—a biostatistician with experience performing complex mathematical calculations—is uniquely qualified to opine about the statistical analyses underlying the Alert does not mean that Drs. Arrowsmith, Ruggieri and Weiss Smith are not qualified to opine about other aspects of the Alert.

Plaintiff offers nothing other than flawed logic to support her *Daubert* argument, and further, the deposition testimony cited by Plaintiff unequivocally demonstrates that these experts are in fact qualified to generally address the Alert. (*See* Pl. Mem. at 4-9.) This testimony is confirmed by a review of the experts' respective credentials and experience. While none of them are biostatisticians, each is qualified to give the opinions he or she provided about the FDA Alert:

- Dr. Arrowsmith is board-certified physician specializing in internal medicine. She has eleven years of experience with the FDA, previously serving as a Medical Review Officer in two different divisions at FDA. In this capacity, she participated in various FDA epidemiologic investigations. (*See* Ex. A, Supplemental Report of Dr. Janet Arrowsmith-Lowe, at 1.)

- Dr. Ruggieri is an M.D. and epidemiologist with a Masters in Public Health. Over the past 20 years, he has gained substantial clinical, computational,

pharmacovigilance and pharmacoepidemiology experience. (*See* Ex. B, Supplemental Report of Dr. Alexander Ruggieri, at 1-2.)

- Dr. Weiss Smith is a Professor in the School of Pharmacy and Epidemiology and Preventative Medicine, School of Medicine at the University of Maryland. She is also currently serving as a visiting scientist at the National Institutes of Health. As an epidemiologist, she has served as a voting member on a number of advisory committees where epidemiologic expertise was needed. As she has previously testified, however, unlike Dr. Gibbons, she is not a biostatistician. (*See* Ex. C, Weiss Smith Dep., at 63.)

Because Drs. Arrowsmith, Ruggieri and Weiss Smith are qualified to opine about the FDA Alert as it relates to their opinions in the instant case, Plaintiff's Rule 702 challenge should be rejected.

II. Pfizer Made No Misrepresentations To The MDL Court When It Sought Leave To Name Dr. Gibbons As A Rebuttal Witness

Plaintiff has not pointed, and cannot point, to any statement by Pfizer regarding Drs. Arrowsmith, Ruggieri and Weiss Smith's qualifications to address the FDA Alert that would make Pfizer's representation that Dr. Gibbons, as a biostatistician with experience analyzing prior FDA meta-analyses, was "uniquely qualified" a "misrepresentation." Instead, Pfizer argued in its request for leave that it was entitled to identify a rebuttal expert to counter new and unforeseen testimony—namely Plaintiff's experts' reliance on the newly released FDA Alert. Pfizer also noted that it should be entitled to name a rebuttal expert capable of analyzing the data underlying the FDA Alert (which at that time had not yet been released). It was Pfizer's right under the Federal Rules to choose—with the MDL court's blessing—Dr. Gibbons.

Not only has Plaintiff failed to identify any "misrepresentation," but her argument ignores the different areas of expertise of Plaintiff's experts and the very facts that make Dr. Gibbons uniquely qualified. As Pfizer noted in its initial motion for leave to name a rebuttal expert, Dr. Gibbons is uniquely qualified to opine on the FDA Alert and data underlying it because:

> He has a Ph.D. in biostatics, has taught biostatics for the past twenty-seven years, and has authored numerous peer-reviewed publications in the field of biostatistics. Not only is he a learned biostatistician, but he is also an expert in psychometrics, or the quantification of behavioral and psychiatric characteristics, and has

> analyzed and quantified suicide events in the context of FDA's review of antidepressant medications for risk of suicide. Indeed, Dr. Gibbons served on the FDA Advisory Committee that considered suicide risk with antidepressant medications.

(Defs.' Mem. [MDL Docket No. 1218] at 10.) None of Pfizer's other experts possess the same qualifications in biostatistics and none have offered biostatistical calculations regarding the FDA Alert. Nor have they provided testimony responding to Plaintiff's statistical expert, Dr. Greenland. Instead, they offer opinions regarding how the FDA Alert and subsequent events further support their opinions in this case.

In sum, Plaintiff has offered no evidence that Pfizer made any "misrepresentations" about its experts.

III. The Opinions of Drs. Arrowsmith, Ruggieri, And Weiss Smith Are Not Cumulative

In yet another attempt to preclude testimony regarding the FDA Alert, Plaintiff claims that the testimony of Drs. Arrowsmith, Ruggieri, and Weiss Smith is "almost identical" to Dr. Gibbons' opinions, and hence cumulative. (Pl. Mem. at 3.) The experts' November 2008 reports are far from "identical" to Dr. Gibbons' reports. Most importantly, Drs. Arrowsmith, Ruggieri, and Weiss Smith do not offer biostatistical calculations, including, for instance, odds ratio and risk difference calculations for Neurontin and other AEDs.

The experts' reports differ in other ways as well. For instance, while Dr. Arrowsmith commented generally on FDA's methodology in her November 2008 report, she performed no mathematical calculations and focused on the issue of warnings from the perspective of a clinician in the field—something that Dr. Gibbons, as a non-medical doctor, did not do. Dr. Arrowsmith, unlike Dr. Gibbons, also commented on Dr. Blume's declaration—submitted by Plaintiff well after the general causation deadline and in the middle of the *Daubert* briefing process. Dr. Ruggeri commented generally on meta-analysis as a methodology and, unlike Dr. Gibbons, responded to Plaintiff's experts' suggestion that Pfizer somehow missed a "safety signal" and should have included additional warnings in Neurontin's label. He also responded to the late-filed declarations of Dr. Blume and of Mr. Keith Altman, an expert, fact witness, and

lawyer for Plaintiff. Finally, Dr. Weiss Smith commented on the flaws in the FDA's analysis, and in the methodologies of Dr. Blume and Mr. Altman, but as a non-biostatistician, did not perform any odds ratio or similar calculations. Accordingly, Plaintiff cannot support her contention that the opinions of Drs. Arrowsmith, Ruggieri, and Weiss Smith about the FDA Alert are "nearly identical" to Dr. Gibbons' opinions and thus "cumulative."

IV. The Expert Reports Of Drs. Arrowsmith, Ruggieri, And Weiss Smith Were Timely

In her final attempt to exclude the opinions of Drs. Arrowsmith, Ruggieri and Weiss Smith, Plaintiff argues that their November 2008 reports are untimely. Conveniently missing from Plaintiff's motion are the deadlines applicable to expert reports in the instant case. Pursuant to Discovery Order No. 26 [MDL Docket No. 1337], Plaintiff's expert reports in *Smith* were due on August 7, 2008. The parties then filed a joint request for extension of the deadlines [MDL Docket No. 1434], which Judge Sorokin granted on September 17, 2008, extending *inter alia*, the deadlines for service of Defendants' expert disclosures to November 10, 2008. The supplemental reports of Drs. Arrowsmith, Ruggieri and Weiss Smith were served on November 10, 2008, in accordance with the MDL court's order, which Plaintiff jointly sought. Thus, Plaintiff's claim that she was "surprised" (Pl. Mem. at 3), when she received supplemental reports from Defendants' experts setting forth additional grounds supporting their opinions in the instant case lacks merit.

CONCLUSION

For all the foregoing reasons, Plaintiff's motion should be denied.

Dated: April 27, 2010

Respectfully submitted,

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

By: /s/ Mark S. Cheffo
Mark S. Cheffo

Four Times Square
New York, NY 10036
Tel: (212) 735-3000

-and-

NEAL & HARWELL, PLC

By: /s/ Gerald D. Neenan
Aubrey B. Harwell, Jr., No. 002559
W. David Bridgers, No. 016603
Gerald D. Neenan, No. 006710

2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219
(615) 244-1713
(615) 726-0573 (fax)

Attorneys for Defendants Pfizer Inc and Warner-Lambert Company LLC

CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
Finkelstein & Partners, LLP
1279 Route 300
Newburg, NY 12550

Charles F. Barrett, Esq.
Barrett & Associates, P.A.
6718 Highway 100, Suite 210
Nashville, TN 37205

Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
W. Mark Lanier, Esq.
Lanier Law Firm
6810 FM 1960 West
Houston, TX 77069

/s/ Gerald D. Neenan